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Specification and Drawings, as originally fil... Application for Patent Serial No: **2,379,268,** on March 26, 2002, by **HANS ... ZMAIL BATKIN AND RICCARDO BRUN DEL RE**, for "Skin I... ce Matched Biopotential Electrode".

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Abstract

A bio-electrode having high volumetric resistivity reduces the effects of noise arising from the 1/2 cell effect.

TITLE: SKIN IMPEDANCE MATCHED BIOPOTENTIAL ELECTRODE

FIELD OF THE INVENTION

This invention relates to bio-electrodes for the pickup of bio-potential signals from bodies or for delivering electrical energy into a body. In particular the invention relates to pickup electrodes that have improved pickup and noise characteristics on skin. The invention also relates to improved bioelectrodes for injecting signals into a body so that localized hot-spots of electrical energy are avoided.

BACKGROUND TO THE INVENTION

Numerous types of bio-signal measurements involve the use of electrodes in contact with a body in order to convey electric bio-signals from the body into a detection apparatus. Important examples are the measurement of electrocardiograms (ECG) and heart rate (HR) on humans.

The majority of bio-signal electrodes are ohmic - i.e. designed to make DC connection to the skin. Ohmic electrodes fall into two broad categories - gel-free electrodes, sometimes called 'dry' electrodes, and gel electrodes (sometimes called 'wet' electrodes).

Prior art prior art 'dry' ohmic electrodes are typically constructed from highly conductive materials such as metals or conductive plastics. Important examples are conductive rubber electrodes used on commercial chest belt HR monitors such as by Polar Electro of Finland or Acumen Inc. of USA. Other examples include metal plate electrodes used for ECG. Electrical connection to the body is established by direct ohmic contact between the highly conductive electrode and the body. Electrodes are this type are sometimes called 'dry' electrodes despite the fact that users are often instructed to

moisten the electrodes with water or specially designed electrolytic solutions before application to skin.

Ohmic electrodes of the 'wet' or gel' type possess an electrolytic gel or paste intervening between the metallic electrode element and the skin. Many examples exist of peel-and-stick electrodes that are pre-gelled and disposable for the purposes of bio-signal pickup such as ECG, EMG (electromyography), EEG (electroencephalography), and for injection of electrical energy into a body such as TENS (transcutaneous electro-neural stimulation) NMES (neuro-muscular electric stimulation) and other applications.

The present invention relates to an improved type of 'dry' electrode that can be used for pickup of bio-signals from a body and for the injection of electrical energy into a body. The invention will be largely described for the pickup application, with particular emphasis on pickup electrodes for ECG. Electrodes for the purposes of the injection of electrical energy into a body can be achieved by minor modification of the electrodes of the invention for the purposes of bio-signal pickup.

All pickup electrodes are used to convey signals originating inside a body to a reading device such as an ECG machine or HR counter. For brevity, the location of the electrical signal inside the body can be called the body-source. The body source, along with the voltage divider required for the pickup of the bio-signal is illustrated in Figure 1 wherein Rsk is the skin resistance, Re is the electrode bulk resistance, and Rs is the sensor input resistance. In the case of passive electrodes connected to an ECG machine Rs represents the ECG machine input resistance. In the case of active, ohmic pickup electrodes possessing an

internal buffer amplifier acting as an impedance converter, Rs represents the net input resistance of the amplifier; including the sensor input biasing resistor.

It is often recommended for bio-signal pickup including ECG that skin preparation such as cleaning, shaving and abrasion be performed to ensure that the skin resistance (Rsk) attains the lowest possible value. The present invention represents a departure from the prior art by providing an electrode that does not require substantial skin preparation to produce high quality signals.

In the case of prior art, low-resistance electrodes applied to the skin for the purposes of ECG, the body source can be considered to be the subcutaneous skin layers carrying cardiac potentials generated by the heart muscle or myocardium. The value of the sensor-to-body source resistance in this case is essentially equal to the intrinsic resistance value of the outer skin layers (Rsk) sometimes called the stratum corneum plus the electrode bulk resistance Re. Representative values for the area-resistivity of skin are 10^4ohm-cm^2 to 10^6ohm-cm^2 [1].

[1] M.R. Prausnitz, Advanced Drug Delivery Reviews, 18 (1996) Elsevier Science p395-425.

For an electrode of total area 10 cm^2 this corresponds to representative sensor-to-body total resistance Rsk in the range 10^3ohm to 10^5ohm. In cases of old, dry skin that is un-abraded, Rsk can surpass 1 Megohm.

Prior art electrode area-resistivities are of the order of 10ohm-cm^2 or less. For an electrode of total area 10 cm^2 this corresponds to an electrode bulk resistance Re = 1 ohm or less. Therefore for ohmic electrodes of the prior art, the

sensor-to-body-source resistance is essentially equal to Rsk because the skin resistance Rsk is typically much greater than the prior art electrode bulk resistance Re.

The value of the intrinsic skin resistance Rsk can depend on many factors including: degree of hydration; pH; the presence of dirt or cosmetics and moisturizing lotions; electrolyte concentration and valence; skin temperature; skin preparation; hair; ambient humidity; time of year; skin disease; thyroid activity and emotional state.

To ensure that the reading device is presented with an effective value of the bio-signal voltage, the sensor-to-body source resistance is preferably much lower than the reading device input impedance. Such a condition ensures that a modest voltage drop occurs due to Rsk. This is a consequence of the nature of the resistive voltage divider of Figure 1 comprised of the skin (Rsk), the electrode (Re) and reading device input (Rs). Preferably the greatest voltage should appear across the largest resistor (Rs). A convenient objective is to provide for 95% of the bio-signal voltage to be present at the reading device input, i.e. the reading device input resistance is preferably 20 times the resistance of the sensor-to-body source contact. This objective is one of the reasons why typical ECG reading devices possess input resistances of on the order of 20Mohms and why prior art electrodes possess small Re values and further require moisture and/or skin preparation protocols such as shaving and abrasion for the reduction of the skin resistance Rsk.

Reading devices with input impedances of on the order 10 megohms and amplification levels or gain of hundreds to thousands of times create problems associated with the lead wires connecting the pickup electrodes to the reading device

inputs. The lead wires can act as pickup antennas for interference signals. Furthermore, motion of the lead wires can cause electrical noise, sometimes called wire-whip artifact. These factors have, in the past, created place further demands to lower the sensor-to-body source resistances in order to allow discharge of these unwanted noise voltages through the body and to ensure symmetrical noise voltage distributions across the body in order to provide optimal common-mode rejection of the noise signals via the common-mode rejection ratio (CMRR) of the reading device.

Since most reading devices have fixed input resistances whereas skin resistance differs widely from person to person and can vary with time on an individual person, and since connecting wires are a source of noise, prior art electrodes have strived to attain sensor-to-body source resistance values as low as possible. As part of this goal, prior art dry ohmic electrodes are made of metallically conductive materials possessing much lower resistivity than human skin in order that the electrode resistance (Re) never contribute significantly to the sensor-to-body source resistance.

The present invention constitutes a departure from the prior art by providing an electrode with a substrate whose resistivity is greater than the resistivity of the skin.

The invention relates to the material properties of the electrode body-contacting layer, also called the electrode substrate. In the following discussion, the term 'metallically conductive' is used to describe materials with electrical conductivity similar to metals. This includes metals, metal alloys, graphite, carbon-black and other materials that display free-electron-type conduction with

volume resistivity between 1 ohm-cm (10^{-2} ohm-m) to 10^{-6} ohm-meter (10^{-8} ohm-cm).

The volume resistivity, rho (ohm-cm) of a material can be converted to a resistance R (ohms) for a particular object made of that material by the formula:

$$R = rho*T/A \qquad (1)$$

where rho is the material volume resistivity, T is the object thickness in the direction of current flow, and A is the total area of the object in contact with the current source.

A significant phenomenon related to metallically conductive materials in bio-signal pickup is the so-called polarization effect, also called "half-cell" or Nernst potential effect. This refers to the battery-like voltage that is generated when a metallic conductor makes contact with an electrolyte. The half-cell phenomenon is due to ions of a particular charge being preferentially attracted to the surface of the metallic conductor thus forming a charged molecular layer in the electrolyte immediately adjacent to the metallically conductive surface. A layer of opposite electrical charge is induced on the metallic surface creating a battery-like potential on the metal.

Skin can be considered an electrolyte because it continuously evolves small amounts of moisture and sweat. Therefore, in the case of prior art ohmic 'dry' electrodes in which metallically conductive materials make direct contact with the skin, a polarization half-cell arises at the electrode to skin boundary.

The microscopic charge layers that embody the polarization phenomenon may be considered to be equivalent to a charged capacitor. It can therefore be said that when a metallically conductive electrode is placed in contact with

the skin, a charged capacitor is spontaneously created at the contact between the electrode and the skin with the capacitor's voltage being none other than the ½-cell voltage. The capacitor's specific capacitance (measured in Farads/cm^2) is determined by electrochemistry and by the skin characteristics. On the basis of physics it can be said that the capacitor's total capacitance (measured in Farads) is proportional to the area of the electrode in contact with the electrolyte.

In the field of 'electrochemical capacitors' or 'double-layer' capacitors, the ½-cell effect is desirable and used to create high-value capacitors by specially designing electrodes with high conductivity and large effective surface area. US patents 5848025 and 6236560 are examples of this.

In bio-signal pickup applications, the opposite situation prevails: it is desirable to reduce the ½-cell voltage and/or reduce the ½-cell capacitance because reducing these factors would reduce the noise-generating capability of the ½-cell, described in the following.

The voltages and specific capacitances (measured in farads per square centimetre) of typical ½-cells relevant to bio-potential electrodes can attain several hundred mV and several uF/cm^2 respectively. Typical bio-signals are of the order of mV.

AC noise is produced from the ½-cell via perturbations of its DC voltage. These perturbations are induced whenever the molecular layers are destabilized by mechanical motion of the electrode or the skin, by sweat permeation into the electrode-to-body boundary, by build-up of oil at the electrode surface, by chemical reactions between other body liquids and the electrode surface, and other effects. In addition to being

generators of electrical noise, these phenomena can lead to additional signal degradation by causing changes in the sensor-to-body source resistance thus leading to changes in signal levels at the reading device input thus causing loss of common mode rejection ratio (CMRR). For bio-potential pickup, both the ½-cell generated noise and resistive noise often possess frequencies of interest to the bio-signal making it very difficult or impossible to filter from the desired bio-signal.

In the discussion that follows, the electrode 'substrate' means the electrode layer that makes contact with the body or the skin; 'electrode' implies either a 'passive' or an 'active' electrode with the distinction being that 'active' electrodes contain a powered electric circuit, while a 'passive' electrode possesses no such circuit but serves as a conductive conduit directly into the lead wires connecting the reading device input or, for signal injection into the body, the signal-generating device output.

Prior art ohmic 'dry' electrodes possess substrates of metallically conductive substances such as metals, powdered metals, or highly conductive composites such as rubber or plastic rendered highly conductive through the addition of carbon black or metal particles. One drawback of these electrodes is that a ½-cell is induced between electrode and skin resulting in signal instabilities and motion induced noise. This greatly restricts use of the electrodes in diagnostic ECG which requires low-frequency components of the cardiac signal 0.05Hz - 100Hz. These types of electrodes are sometimes sufficient for short-term, resting ECG on some skin types but are not able to produce good signals on all skin types or motion-robust signals. The present invention

represents an improvement over the prior art by enabling pickup at rest and under motion on all skin types.

In the case of HR pickup the input impedances of existing devices are usually lower than typical ECG devices inputs, with HR device inputs often being less than 2 Mohms. This facilitates the discharge of electrode noise. Furthermore the HR signal is derived from a sub-band of the diagnostic ECG signal - approximately 5Hz - 20Hz and is therefore more tolerant of background noise. For this reason prior art 'dry' electrodes are sufficient for heart-rate (HR) pickup on the majority of skin types. However prior art HR electrodes devices often fail to operate satisfactorily on highly resistive skin due to the voltage divider constraint described above. The present invention represents an improvement over the prior art electrodes for HR pickup by allowing signal acquisition on skin of high resistance and by improving the signal to noise ratio.

For diagnostic ECG, prior art 'wet' electrodes minimize half-cell noise by electromechanically stabilizing the ½-cell. This is accomplished by providing a chloridated silver or anodised coating to the metallic electrode element and by further providing a layer of viscous, or semi-solid electrolytic paste or gel between the treated metallic element and the skin. Direct contact between the skin and metallic conductor is avoided allowing the formation of stable ½-cell layers at the interface between the metal and the gel or between the metal and the gel-impregnated chloridated layers. These types of stabilized ½-cells create stable DC levels with little AC component in the ½-cell voltage but they create the drawbacks of messiness, skin irritation, deterioration of electrode over time, and desiccation of gel when exposed to

air. Furthermore gel-based electrodes are not easily re-usable and unsuitable for the construction pre-formatted electrode arrays or modules that can be removed and re-donned at the user's discretion.

The present invention addresses an alternate form of dry active electrode that exhibits a reduced level of ½-cell noise.

The invention in its general form will first be described, and then its implementation in terms of specific embodiments will be detailed with reference to the drawings following hereafter. These embodiments are intended to demonstrate the principle of the invention, and the manner of its implementation. The invention in its broadest and more specific forms will then be further described, and defined, in each of the individual claims which conclude this Specification.

SUMMARY OF THE INVENTION

According to the invention a bio-electrode is provided that possesses a high-resistivity (low conductivity) substrate at the body-to-electrode interface that reduces the ½-cell effect when compared to highly conductive materials. Such electrodes provide inputs to electronic circuitry with a very high input impedance, Rs. The total electrode substrate resistance (Re) is equal or larger than typical skin resistances (Rsk). Preferred embodiments of the invention employ active pickup electrodes for the purpose of ECG pickup. An 'active' pickup electrode possesses an internal on-board circuit performing as an impedance converter. This is combined with a voltage divider, and a shielding means.

The present invention provides the advantages of reducing electrolytic noise generated at the electrode-to-skin contact while at the same time enabling signal pickup on unprepared skin of high Rsk that would disrupt conventional electrode operation. A further advantage of the active electrode variant of the invention is the reduction of cable noise because the electrode impedance converter reduces the effective impedance in the lead wire portion of the circuit, thus reducing the effects of interference and wire motion.

With minor modifications, electrodes of the invention can be used to transmit electrical signals into a body with the advantage of increasing the homogeneity of the signal distribution into the skin. This is because the high resistivity of the electrode substrate of the invention acts as a distributed resistor that limits the formation of regions of high current density at the electrode edges or at localized, low-impedance regions of skin. Such 'hot-spots' are a well-known problem for prior-art, highly conductive ohmic electrodes used for signal injection.

In a preferred variant, an active pickup electrode is constructed using a body-contacting layer or substrate comprised of a material with volume resistivity in the range 10^4 ohm-cm (10^2 ohm-m) to 10^{10} ohm-cm (10^8 ohm-m), more preferably above 10^6 ohm-cm. This range of volume resistivity is orders of magnitude higher than prior art ohmic electrodes constructed from metals or from highly conductive carbon-impregnated rubber or plastics.

For electrodes of the invention operating at the upper range of resistivity of the invention, i.e. approaching 10^{10} ohm-cm, it is desirable to incorporate a shield layer electrically connected to the reference voltage point in the

circuitry. This shield should lie above the impedance converter and it should partially enclose the impedance converter and the body-non-facing side of the electrode.

In order to prevent accidental connections to ground and signal shunting to ground in the presence of moisture, it is desirable to encapsulate and waterproof the electrode except for the body-facing surface of the substrate. The encapsulant can optionally extend to the body-facing surface as a ring surrounding the body facing side of the substrate.

An example of a desirable substrate material is sheet rubber or plastic material that has been rendered slightly conductive with the addition of carbon black. Microscopically, such materials represent a non-conductive matrix with embedded conductive particles such as carbon-black. These have the advantage of low-cost, resistivity that can be predicted based on the amount of carbon black added during their manufacture, amenability to mass production processes, mechanical flexibility, chemical inertness, biocompatibility, and low cost.

The upper limit of the regime of substrate resistivity of the invention, i.e. 10^{10} ohm-cm defines the practical limit for the realization of the advantages of the invention. This is because the advantages of the high resistivity substrate, namely the reduction of ½-cell effects are countered by the onset of a secondary noise generation mechanism i.e. triboelectricity, also called static electricity, that is formed by the contact between the virtually insulating electrode substrates and the body. Noise results from local variations in static charges resident on the body, or disturbed, surface or which are induced on the body during motion. As the substrate resistivity increases above the

order of magnitude 10^{10} ohm-cm and the corresponding Rs increases above the order 10^{11} ohms, the reduction in the ½-cell effect becomes counter balanced by the increasing significance of triboelectric charges and surface charge effects which create noise voltages.

Concurrent increases in the circuitry effective input impedance as determined by Rs creates a situation whereby the discharge times for these noise sources also increases. In fact, electrodes with substrate resistivity above the order 10^{10} ohm-cm begin to operate akin to a capacitive mode and it can be said that electrodes for the purpose of ECG in this condition operate in a 'crossover' regime, tending towards fully capacitive operation.

It has been found that experiments with electrodes of low-capacitance type as specified in PCT application PCT/CA [illegible] that the fully capacitive operation is realized with substrate resistivities greater than 10^{14} ohm-cm and input biasing Rs values of the order 10^{12} ohms.

The foregoing summarizes the principal features of the invention and some of its optional aspects. The invention may be further understood by the description of the preferred embodiments, in conjunction with the drawings, which now follow.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a circuit showing the electrical pathway for the pickup of a bio-signal with the body source illustrated as a generator, producing signal Vh.

Figure 2 is a cross sectional view of an electrode according to the invention for the purposes of ECG pickup.

Figure 3 is a photograph of an electrode of the invention for the purpose of pickup of ECG.

Figure 4 shows a two-electrode module possessing two electrodes of the invention of the type illustrated in Figure 3 and which are incorporated into a chest-belt.

Figure 5 shows two simultaneous ECG traces obtained on a patient. The traces were recorded using two identical, single-channel commercially available event recorders possessing proprietary two-lead wire cables terminating in standard female dome connectors customary for ECG electrodes. The upper trace shows the signal derived from a two medical adhesive gel electrodes applied to cleaned, abraded skin of the patient and subsequently connected to one of the identical event recorders. The lower trace shows the signal obtained by connecting the second of the identical event recorders to the electrode module illustrated in Figure 4. No connection to the ground dome on the electrode module of the invention was employed for acquisition of the traces. During the time of the recording, the patient was in a state of motion.

Figure 6 is a graph of calculated data from Table 1 by which the ½ cell discharge time constant (t = Cn (Re + Rs) is plotted as a function of electrode substrate volume resistivity.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 shows the body internal electrical source such as the heart as a signal generator Vh. Sensing of Vh is accomplished between point F, representing the electrode or 'pickup' location and point K representing the 'return' or reference voltage location. The total resistance between the electrode and the body source is approximately given by the

bulk electrode resistance Re, representing the substrate resistance, plus the skin resistance Rsk. The noise generating aspect of the ½-cell is modelled as a capacitor Cn and battery with fixed dc voltage Vn which is randomly switched into and out of the circuit via switch S. The capacitance Cn and battery voltage are spontaneously created upon contact between the electrode substrate and the skin.

The electrode substrate presents a total resistance to body Re given by the formula Re = rho*T/A where rho is the substrate volume resistivity, T is the substrate thickness, and A is the total substrate area in contact with the body. The source Vh in Figure 1 can be considered to be an internal organ or the subcutaneous skin layer that carries the voltages generated by that organ. The resistances from the signal source Vh to the outer skin layer, also called stratum corneum, are Rsk1 and Rsk2. These resistances are mainly focussed at the locations F and K respectively on the body.

Outside the body, the electrode is represented by the bulk electrode resistance Re. The electrode-to-body interface is represented by a half-cell capacitance Cn and switch S1 which randomly charges Cn with the ½-cell DC voltage and subsequently discharges Cn into the voltage divider. The sensor resistor Rs of the detection circuitry represents the resistance across which the bio-signal is sensed. This is an internal input-biasing resistor in the case of an active electrode or it is the reading device input resistance in the case of a passive electrode. The resistors Rsk1, Rsk2, Re, and Rs are the resistances that constitute the ohmic voltage divider for pickup of the bio-signal voltage between the electrode location F and the reference voltage location K.

As seen in Figure 1, the electrode bulk resistance Re together with the input resistor Rs and Rsk1, Rsk2 comprise a resistive voltage divider for the bio-signal voltage arising between the electrode location and the reference voltage location. The impedance converter senses the voltage appearing across Rs. The value of Rs may be chosen by the requirement that the electrode output signal Vs should be at least generally equal to that of the body voltage Vh. When Rs is much greater than Rsk the electrode output signal Vs is approximately governed by the relationship:

$$Vs = Vh\ [Rs/(Re+Rs)] \qquad (2)$$

where Vh is the body voltage and Vs is the sensed voltage (across Rs). For example, if it is desired that Vs should be in magnitude 95% of Vh, then Rs should be 20 times the value of Re. For reasons analogous to those discussed above in connection with impedance of typical reading devices, the resistor Rs should not be much larger than that required to satisfy signal size requirement because overly large Rs can introduce noise or compromise the desired signal-stabilizing and referencing properties of the invention.

The reference voltage, which is the body voltage at point K, is established via a reference electrode placed at the surface of the body at point K. The desirable impedance of the reference electrode-to-body contact at point K is determined on the basis of common-mode requirements of the monitoring apparatus utilizing dual pick-up electrodes (not illustrated). According to the above discussion it should be understood that in the preferred embodiment, the sensor includes on-board electrode impedance converting means such as an operational amplifier. Depending on the body signal frequency and the monitoring apparatus grounding requirement

and CMRR, the reference electrode at point K can take the form of a passive electrode of either ohmic or capacitive type, or in some cases the reference electrode at location K can be established with an equivalent, active electrode of the invention as the pickup electrode at point F.

Figure 2 illustrates a cross-sectional view of a coin-shaped or disc-shaped electrode of the invention. The electrode is encapsulated with an insulating layer 1 which is electrically resistive and waterproof. Several encapsulating materials including epoxy, plastic and rubber compounds have been found suitable for this purpose. The electrode possesses an internal conductive cap acting as a shield 2, which is 'grounded' i.e. connected to the reference potential. A cable 3 carries power to, and signal from the on-board electrode circuit 4. The circuit 4 is fixed on a 2-layer printed circuit board 5 with a bottom conducting layer 6 serving as the ohmic contact with the substrate layer 7.

A preferred material for substrate layer 7 is a moulded-rubber sheet containing a suspension of colloidal graphite to render it mildly conducting according to the invention. Various mixtures with desirable resistivities can be made in accordance with the teachings of "Conductive Rubber and Plastics, R.N. Norma, Elsevier Publishing Co. Amsterdam 1970". Successful electrodes have been constructed using EPDM neoprene and silicone-based rubbers that are rendered slightly conductive with carbon-black, or with other conductive additives. These materials are 'anti-static' according to static industry standards. The invention therefore relates to any substrate materials possessing homogenous, bulk conductivity of the desired value.

The substrate layer 7 is bonded to the conducting layer 6 by way of a conductive adhesive. Alternately, substrate layer 7 can be painted or moulded onto the circuit board conducting layer 6. The substrate layer 7 may have a volume resistivity in the range 10^4 ohm-cm to 10^{10} ohm-cm, which is the primary feature of the invention. Substrate layer 7 limits the total electrode-to-skin resistance to a value given by the formula above.

For the special case of an electrode possessing a substrate layer 7 of thickness 1mm and total surface area $10cm^2$, the total electrode resistance Re is precisely equal to a value in ohms equal to one hundredth the numerical value of the volume resistivity of material 7 in ohm-cm. In other words, a $10cm^2$ electrode possessing a 1mm thick layer of 10000Mohm-cm substrate material displays an electrode bulk resistance of 100Mohm. Circuit element 8 is the resistor Rs, which is connected to the reference potential via circuit traces on the circuit board 5. The insulating layer 1 may extend to a point along the outer edges of the electrode so as to present an insulating ring around the substrate on the body-facing side of the electrode. The circuit 4 is a high input impedance electrical device in the form of an operational amplifier or the like which serves as an impedance converter. The output from the circuit 4 is sent to the external reading device (not shown) via cable 3.

Figure 3 shows a photograph of the electrode specified in Figure 2. The substrate of the electrode of Figure 3 is an EPDM neoprene rubber with resistivity of order 10^{10} ohm-cm and an approximate area of $6cm^2$. The Re value of this electrode is approximately 100Mohms and the electrode possesses an internal Rs of value 1Gohm.

Figure 4 shows a modular electrode array designed for use with elastics attached by hook-and-loop connectors that together comprise a chest belt support for the electrodes of the invention. The module consists of the two active electrodes of the invention connected to an encapsulated, self-contained battery supply with a grounding electrode, also called the sternum plate, on its body facing side for referencing the self-contained battery supply to the patient's body. The outputs of the electrodes are connected to standard type male dome connectors on the body-non-facing side of the electrodes. A third electrode dome output for the sternum plate is connected to the circuit ground and is sometimes used for referencing between the electrode module and bench-top ECG machines.

Figure 5 shows simultaneous signals obtained from clinical gel 'wet' electrodes applied to skin of a patient previously prepared at the gel electrode sites according to standard protocols for ECG (top trace), compared to the electrodes of the invention which were moistened with a damp sponge and applied to adjacent unprepared skin of the same patient (bottom). The signal quality is significantly higher in the case of the electrodes of the invention in that less noise is present.

Electrodes of the invention have the advantage of producing very low ½-cell noise. This is believed to be due to the poor conductivity of the substrate on the following basis. This basis is presented as a theory that need not necessarily be correct.

An electrode of the invention can be envisioned as a parallel array of many microscopic electrodes seen as series elements extending from the body-facing side of the substrate

to the sensor input. Each element can be considered to terminate on a small capacitor Cn′, representing the ½-cell capacitance due to the contact between the small element and the body. Each electrode element also comprises a resistor Re′ representing the resistance of the overlying substrate layer responsible for conducting the bio-signal into the sensor. The complete electrode is a parallel network of such elements with combined ½-cell capacitance Cn equal to the sum of all the Cn′ and combined resistance Re arising from a parallel sum of all the Re′.

An electrode of the invention with high resistivity (low conductivity) can be considered to be a microscopic network of a few parallel electrode circuits suspended in relatively large islands of non-conducting matrix. Since the total ½-cell capacitance generated by the electrode is the sum of the elemental capacitances, a substrate with high resistivity (low conductivity) produces a lesser total Cn than an electrode of substrate with low resistivity (high conductivity).

As a first approximation the ½-cell capacitance is proportional to the substrate surface conductivity, which is inversely proportional to the substrate surface resistivity. According to the physics of homogenous media, the surface resistivity is equal to the volume resistivity raised to the power 3/2. Experimental data on plastics rendered partially conductive with the addition of carbon black or colloidal graphite indicate that the observed power is 1.5 +/- 0.1 [2].

[2] Conductive Rubber and Plastics, R.N. Norma, Elsevier Publishing Co. Amsterdam 1970

This shows that such materials can be approximated as homogenous conductors for the purposes of their bulk

properties despite the fact that these materials are inhomogenous on the microscopic scale at which the above argument relating to Cn' is approximately valid.

Referring to Figure 1, electrode noise is modelled as a capacitor Cn that is charged to a battery voltage representing the ½-cell voltage via a switch S1 which subsequently switches to allow Cn to discharge through the sensing circuit. The total discharge time for the ½-cell capacitance Cn through the voltage divider of the sensing network is a measure of the noise-generating capability of the electrode ½-cell. This discharge time is proportional to Cn times the sum of Re and Rs, assuming Rsk to be relatively small compared to Rs.

Table 1 compares the theoretical ½-cell capacitance discharge time t = Cn*(Re+Rs) of several electrodes possessing substrates of thickness l = 0.1cm, and area A = 10 cm^2. Electrode bulk resistances Re as shown on the table are determined from volume resistivity on the basis of formula 1. Also shown on the table are the values of area-resistivity for the electrodes which is the volume resistivity multiplied by the electrode area, in order to allow direct comparison with skin area-resistivity values quoted in scientific literature. In Table 1, the ½-cell capacitances Cn for the electrodes are extrapolated from a value of 1uF for a highly conductive carbon-impregnated rubber using the surface resistivity power-law described above. In the two entries on Table 1 labelled 'prior art', a range of Rs values from 2Mohm to 100Mohm is given as representative of commercial ECG and HR devices.

The same range of Rs values is used in the cases labelled 'Poor' (i.e. 'Plastic 1') and 'Intermediate' (i.e. 'Plastic 2'). In these cases the total electrode resistance values Re for electrodes of dimension as specified on the table render

Rs values according to the voltage divider criterion (Rs equal 20 times Re) which are too small to allow signal pickup on skin possessing resistance Rsk approaching or exceeding 1Mohm. Electrodes coupled with such Rs values fail to manifest one advantage of the invention which is to enable signal pickup on resistive skin. Furthermore the entry labelled 'poor' shows no significant improvement over prior art discharge times when combined with Rs values in the range or conventional reading devices. On the other had, the entry labelled 'intermediate' shows ½-cell discharge times that are favourable compared to the prior art for some Rs values in the same range. In particular the discharge time corresponding to a sensor input resistances of less than 20Mohm can be seen to provide significant improvement over the prior art while higher values of Rs provide lesser advantages.

The four cases in Table 1 labelled 'Hi-Q' (i.e. 'Plastic 3' through 'Plastic 6') illustrate the optimal regime of the invention. In these cases the Rs values have been chosen according to the preferred minimum 'voltage divider' condition (Rs = 20 times Re). It can be seen that in these cases the half-cell discharge time is extremely short indicating a minimized noise generating capability of the electrode while the Rs values shown span the range of conventional reading device input resistances indicating equal or better voltage divider characteristics compared to prior art electrodes.

Table 1 -Rubber Electrode. Cn = 1uF. Substrate area = 10cm^2, thickness =0.1cm.

Material	Rho (ohm-cm)	Re (ohm)	Re' (ohmcm^2)	Cn uF	Rs (Mohm)	Cn(Re+Rs) (seconds)
Prior art						
Conductive Silicone	100	1	100	1	2 - 100	2 - 100
Poor						
Plastic 1	1.0×10^4	1.0×10^2	1.0×10^4	0.05	2 -100	0.1 - 5
Intermediate						
Plastic 2	1.0×10^6	1.0×10^4	1.0×10^6	0.002	2 - 100 20	4×10^{-3}-0.2 0.04
Hi-Q						
Plastic 3	1.0×10^7	1.0×10^5	1.0×10^7	5×10^{-4}	2	1×10^{-3}
Plastic 4	1.0×10^8	1.0×10^6	1.0×10^8	1×10^{-4}	20	[illegible]
Plastic 5	1.0×10^9	1.0×10^7	1.0×10^9	2×10^{-5}	200	[illegible]
Plastic 6	1.0×10^{10}	1.0×10^8	1.0×10^{10}	5×10^{-6}	2000	1×10^{-2}

Figure 6 shows in graphical form, the data for the ½-cell discharge time Cn(Re+Rs) vs the electrode substrate volume resistivity as these appear in Table 1.

For simplicity in the preceding, it has been assumed that the ½-cell voltage remains constant, independent of the substrate resistivity. The noise-reducing benefits of the invention were related to the reduction in the ½-cell capacitance as a function of increasing substrate volume resistivity. However, it is expected that in certain cases, substrates of low-conductivity can produce ½-cells of voltages lower than those produced by similar materials of higher conductivity. This leads to a second-order noise-reducing benefit of the invention in some cases.

CONCLUSION

The foregoing has constituted a description of specific embodiments showing how the invention may be applied and put into use. These embodiments are only exemplary. The invention in its broadest, and more specific aspects, is further described and defined in the claims which now follow.

These claims, and the language used therein, are to be understood in terms of the variants of the invention which have been described. They are not to be restricted to such variants, but are to be read as covering the full scope of the invention as is implicit within the invention and the disclosure that has been provided herein.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An electrode for obtaining or providing electrical signals from or to the human body wherein the volume resistivity of the substrate material of the electrode in contact with the body is in the range of 10^4 ohm-cm to 10^{10} ohm-cm.

2. An electrode as in claim 1 wherein the volume resistivity of the substrate material of the electrode in contact with the body is in excess of 10^6 ohm-cm.

3. An electrode as in claim 1, or 2, in which the substrate comprises a non-conductive matrix rendered partially conductive in the range of the invention with the addition of conductive additive that forms conductive pathways within the non-conductive matrix.

4. An electrode as in claim 3 wherein the conductive additive is carbon black.

5. An electrode as in claim 1 or 2 comprising a shield overlying the electrode, said shield being:

(a) provided with an insulating gap to prevent its contact with the electrode substrate;

(b) coated or embedded in a insulating and waterproofing material; and

(c) electrically connected to the electrode reference potential.

6. An electrode as in claim 1, or 2, comprising a layer in the form of a varnish or rubber compound rendered conductive with the addition of carbon black or other anti-static compounds.

7. An electrode as in claim 1 in combination with a high input impedance conversion circuit that is carried by the electrode itself.

8. An electrode and circuit combination as in claim 7 wherein the impedance conversion circuit has an impedance of in excess of 2×10^7 ohms.

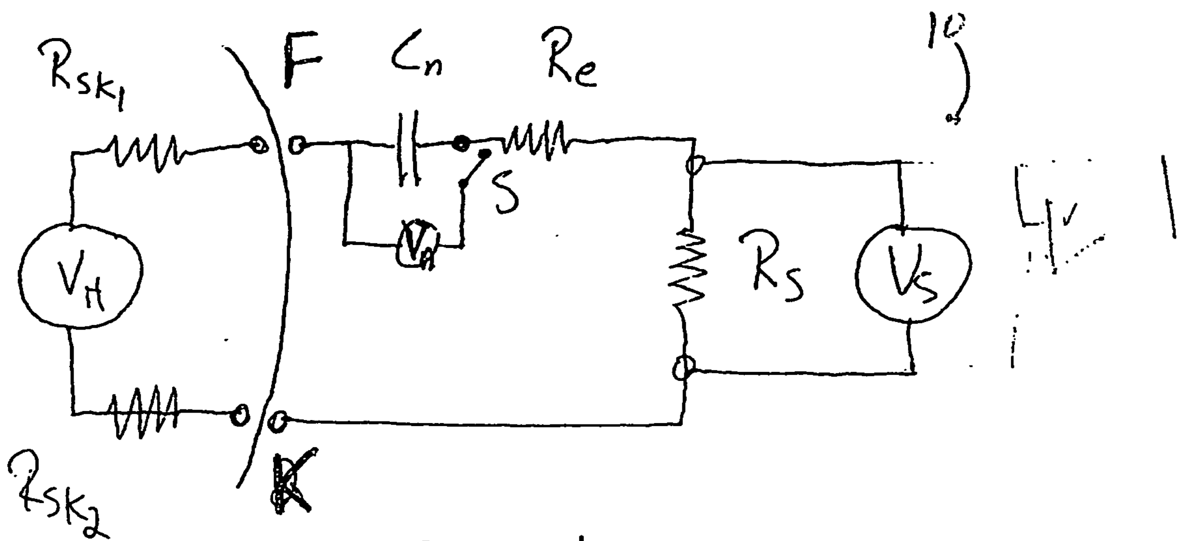

Figure 1

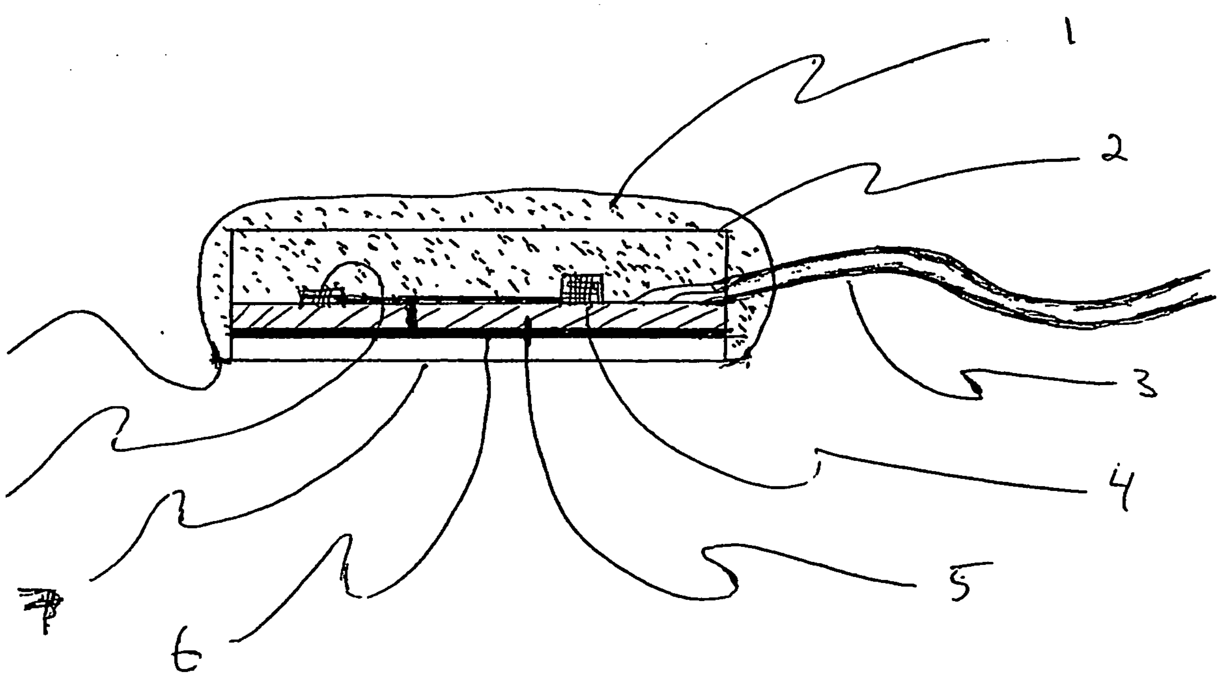

Figure 2

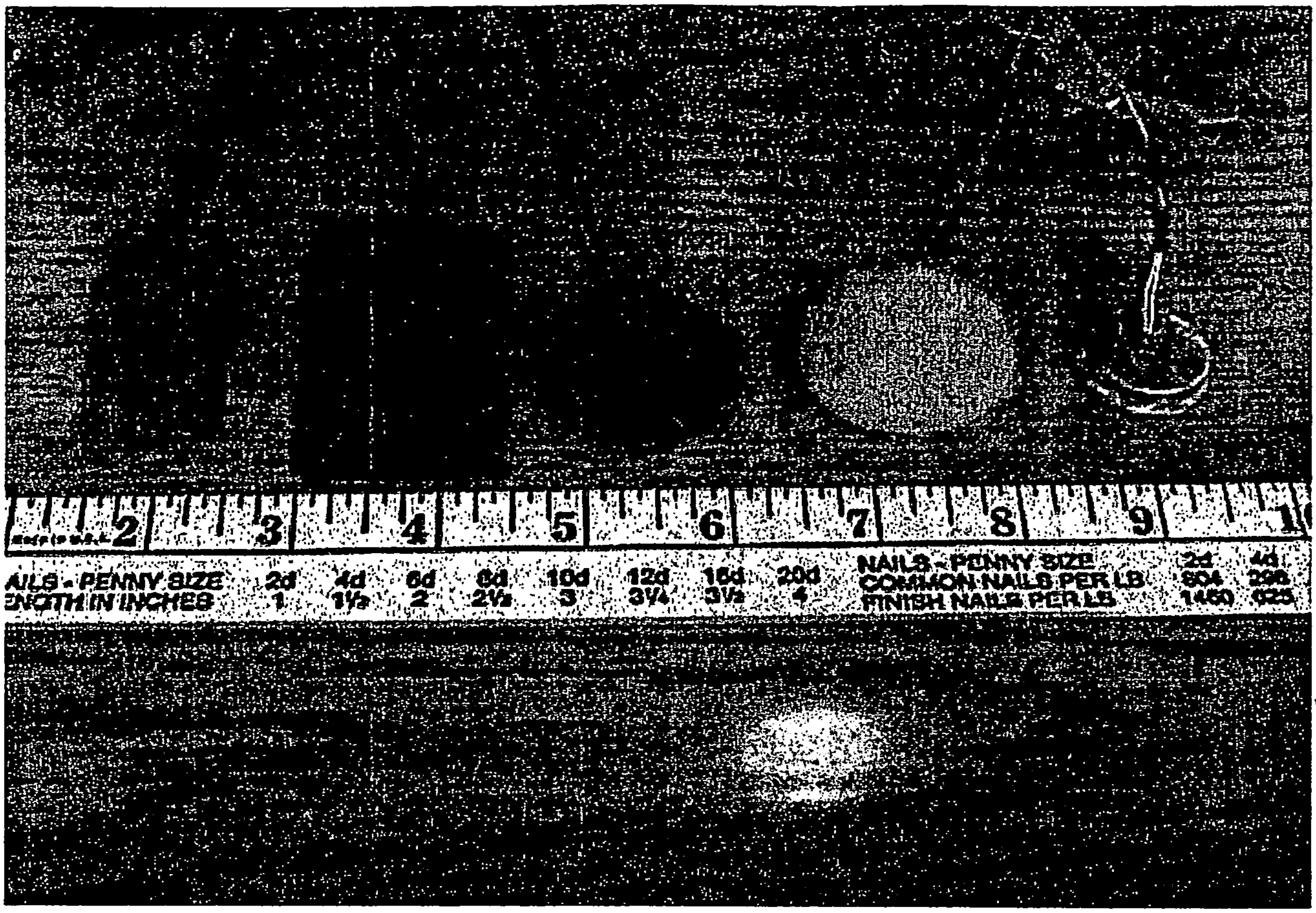

Figure 3.

Electrode of the invention is middle electrode (black disc)

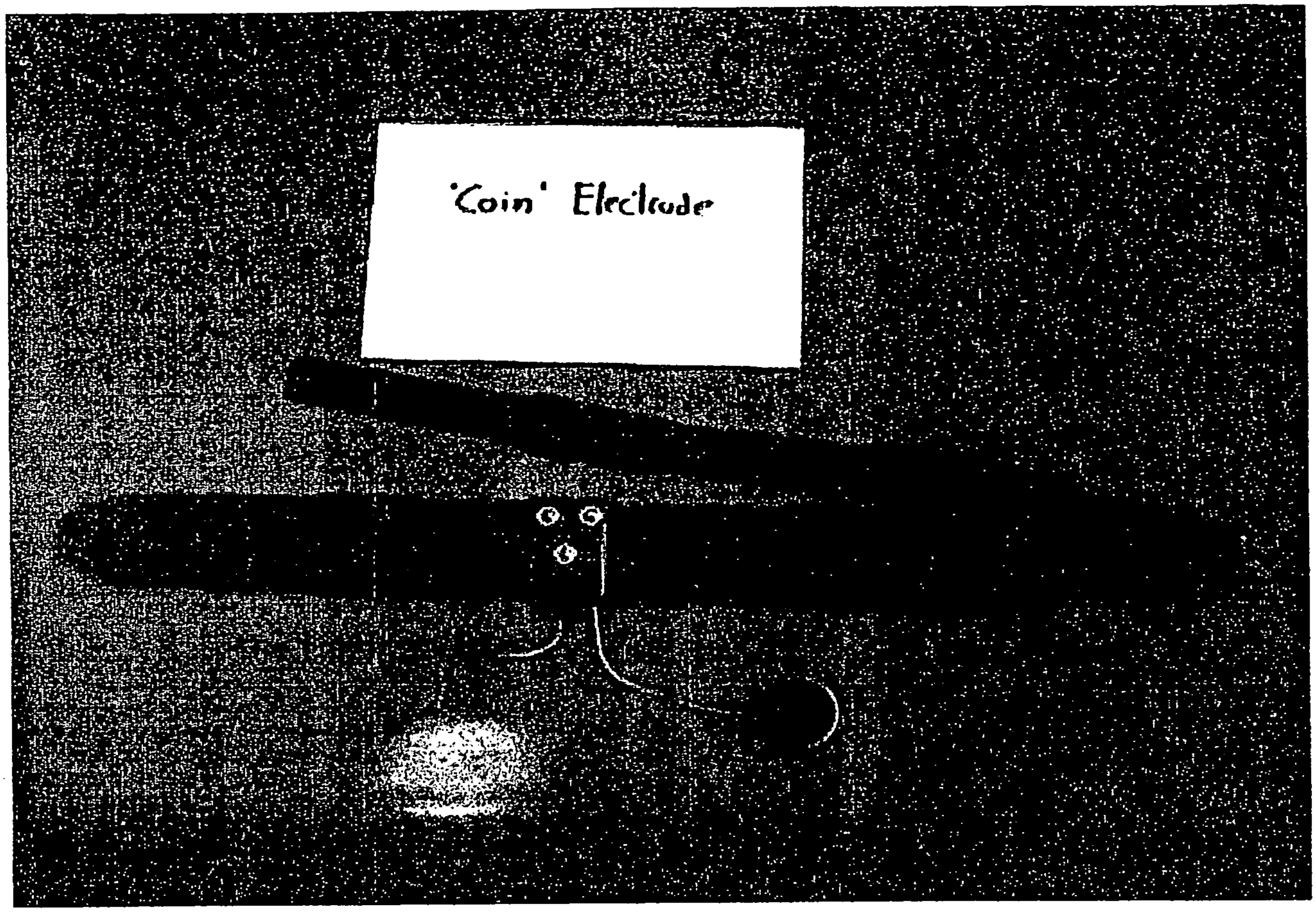

Figure 4 Electrode chest belt module

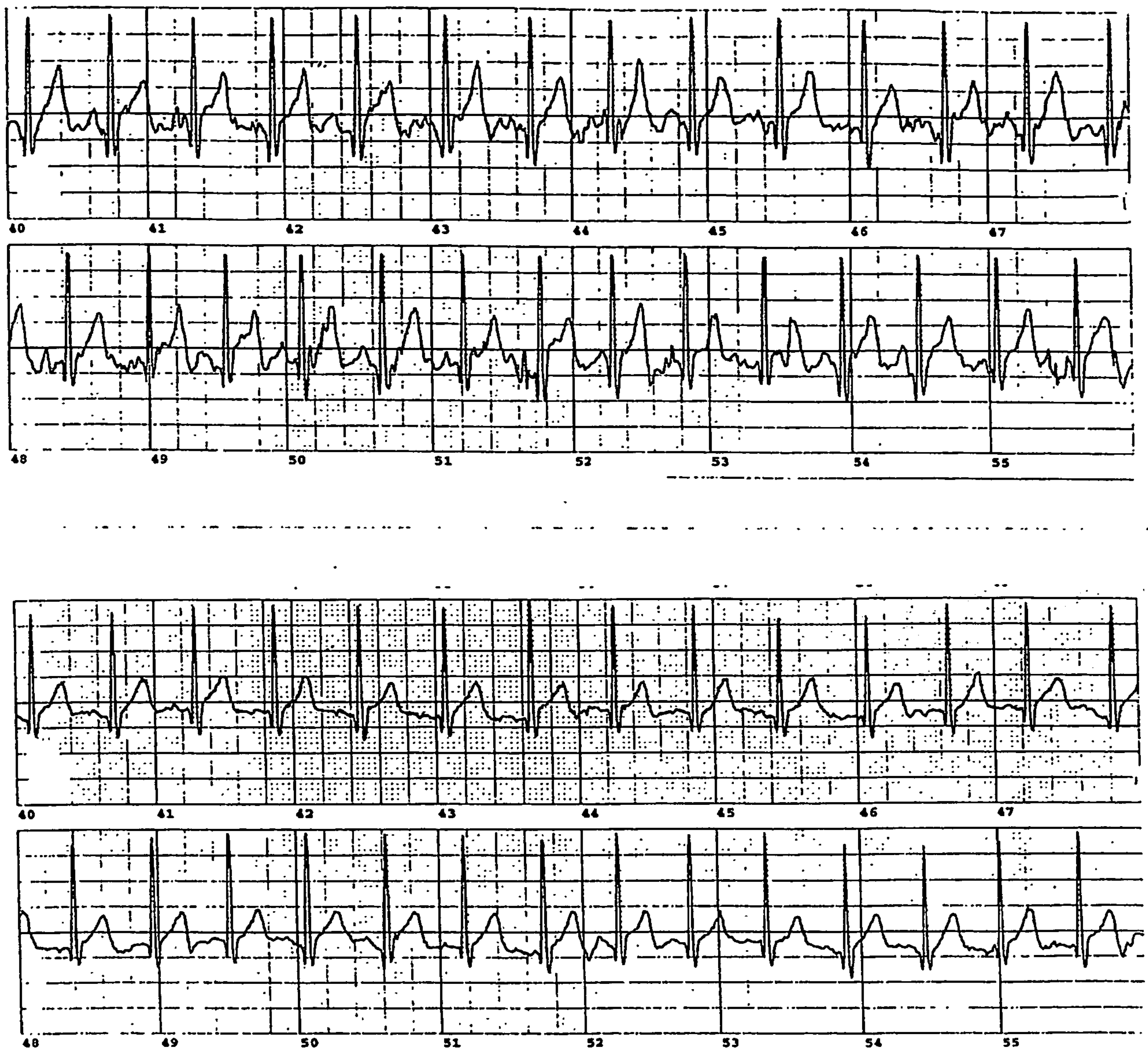

Figure 5 Simultaneous ECG using gel electrodes (top) and Hi-Q electrodes (bottom) during patient motion.

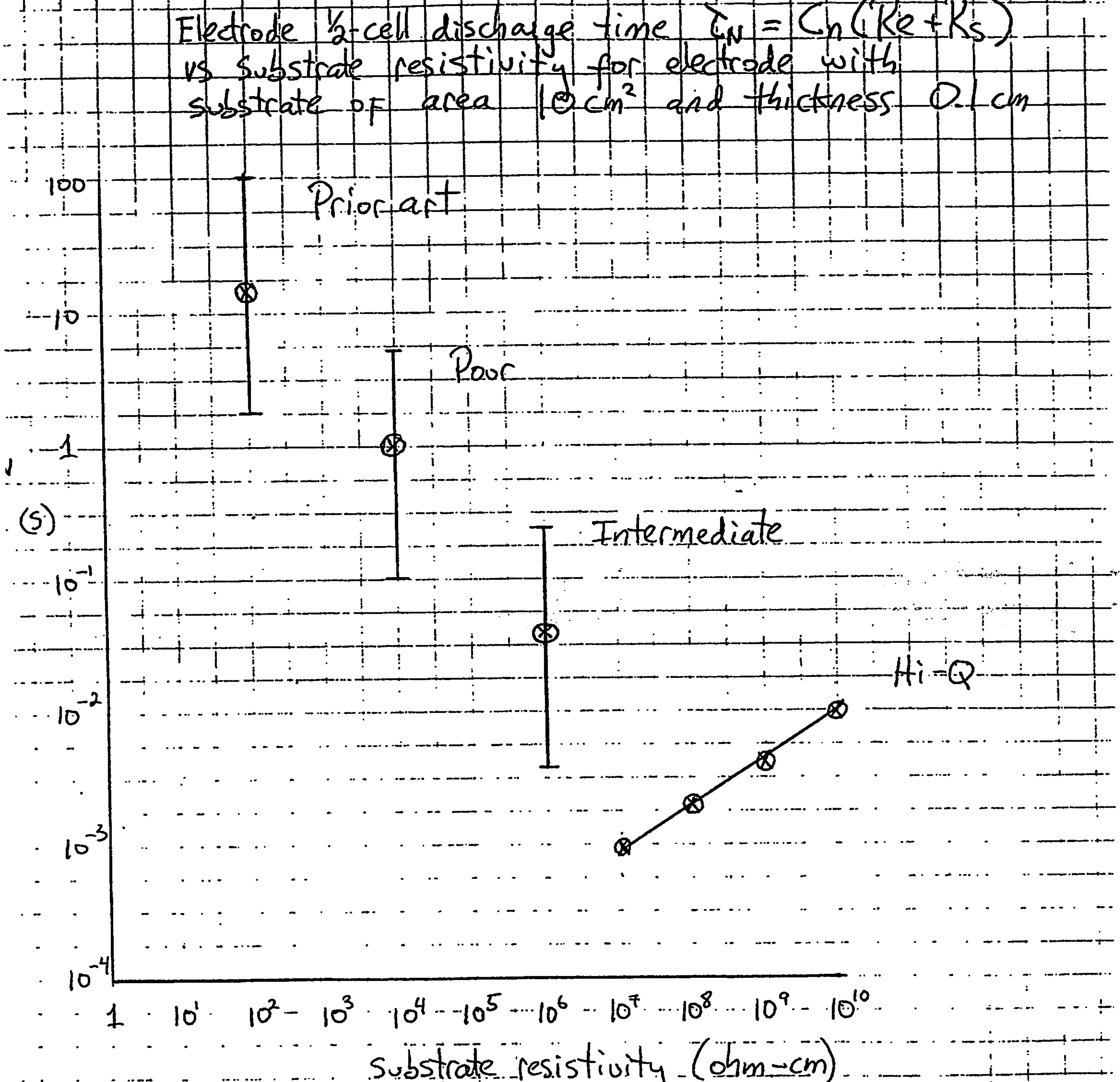

Figure 6. Electrode ½-cell discharge time vs. substrate resistivity. Data according to Table 1.

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